

KOLKOTTA DECLARATION on PHARMACEUTICAL POLICY

The National Seminar on Pharmaceutical Policy and Access to Essential Medicines organised by Jan Swasthya Abhiyan, Federation of Medical and Sales Representatives' Associations of India, National Campaign Committee for Drug Policy and All India Drug Action Network and supported by the World Health Organisation, India country office discussed different aspects of the country's pharmaceutical policy. The seminar was attended by one hundred and twenty eight activists, academics and experts from all parts of the country that deliberated on different issues related to the pharmaceutical sector in India.

The Seminar noted that the country's record in controlling diseases that affect large sections of the people has been far less than satisfactory. The country faces new challenges in the form of increased incidence of "lifestyle" diseases and infections such as HIV-AIDS. This ominous situation admitted in the National Health Policy-2002 needs to be addressed seriously. Disease pattern and common ailments highlighted in NFHS-2 survey should also be taken in consideration.

The seminar also noted the new situation created by the policy of globalisation, privatisation, liberalization and the new product patent regime which together have threatened the national self reliance as well as availability and affordability of essential medicines. The seminar also felt concerned about the worsening situation on the drug price front with its disastrous impact on the poor.

Given the above the Seminar resolves the following suggestions be considered while making the National Pharmaceutical Policy.

Formulation of National Pharmaceutical Policy:

The seminar expressed the need to formulate a National Pharmaceutical Policy that addresses the critical issue of universal access to essential medicines and of national self-reliance. This policy should be prepared by an intersectoral committee of the Ministry of Health & Family Welfare and Ministry of Chemicals & Fertilizers after discussions with all sections that have a stake in the pharmaceutical sector. The two should jointly constitute a National Drugs and Therapeutic Authority, which should be a statutory body with powers to regulate all aspects of the National Pharmaceutical Policy. Apart from experts, this body should also include representatives from health movements.

National Essential Medicines List

1. The Govt., based on epidemiological data, should update the National Essential Medicines List (NEML) and also prepare a Graded Essential Medicines List that is appropriate for each level of the health care system. The National List needs to be adopted by different states and adapted by them based on local conditions and disease profile.
2. The Govt. should monitor and ensure the availability of Medicines listed in the EML. Production of these medicines from the basic stages should be ensured through production control mechanisms.
3. It should be made mandatory that the procurement and use of medicines in Govt. hospitals and public sector undertakings be done based on the NEML. Such procurement should be through transparent procedures. Regular training and incentives to promote use of medicines in the NEML should be provided.

Irrational and Hazardous Drugs

1. Given the proliferation of irrational and hazardous medicines in the market, a special committee of the DTBA should be set-up to weed out all such medicines including irrational Fixed Dose Combinations (FDC) within a stipulated period. Hence forth medicines and fixed dose combinations which are not mentioned in standard text books and other such authentic sources of pharmacological information should be banned and should not be allowed to be marketed. All existing medicines should be re-evaluated at regular intervals on the basis of expert opinion on their rationality, efficacy and need.
2. Injectable contraceptives, transdermal implants and anti fertility vaccines should not be used in the National Family Planning Programme.
3. Adverse Drug Reaction (ADR) Monitoring Centres should be set up in all states of the country and be provided with sufficient resources.
4. When a substantial number of ADRs are reported either in India or abroad for a drug, the same should be referred to the DTAB for withdrawal.

Generic Drug Use

In order to encourage use of medicines in generic names, all medicines sold under generic names should be exempt of duties and taxes. All packages of medicines should carry the generic name more prominently than the brand name.

Medical Education

The curriculum for medical education should include the concepts of essential drugs and rational prescription practices.

Indian Patents Act

1. The Govt. should keep advocating for keeping TRIPS out of WTO provisions and advocate for reopening the issue of exempting the developing countries from Product Patent.
2. The Govt. should ensure that all the flexibilities in the Act are used to promote health and development of the indigenous drug industry.
3. The Govt. should closely monitor the application of Patentability criteria for granting of Patents to ensure that trivial Patents are not allowed and ever greening of existing Patents does not take place.
4. The Govt. should liberally interpret the Doha Declaration of 2001 by declaring situations of emergency/urgency in the case of diseases that are present in epidemic or endemic forms or where their prevalence constitutes a health emergency. In such situations Compulsory licenses should be issued without delay.
5. Govt. should also facilitate the issue of compulsory licenses to remedy situations of non availability or high price of a patented drug or where an export market exists and is not being addressed.

Drug Production and Availability

1. To ensure production from the basic stage, ratio parameters between manufacture of formulation and bulk drugs should be reintroduced.
2. Production Control mechanisms should be introduced to ensure that all manufacturers produce a certain proportion of drugs from NEML that are Essential.
3. The new policy of allowing 100% equity participation of MNCs in the pharmaceutical sector needs to be changed and majority equity participation by the multinational companies should only be permitted if new technology is brought in by them for manufacturing and research.
4. Restrictions in the form of tariffs and other non-tariff measures should be imposed on the import of bulk drugs or formulation for which adequate production capacities exist in the country.
5. Prevailing systems of loan license or third party license should be abolished. Mention of the name and address of the manufacturer should be clearly indicated on the label of each medicine, and the license holder should be held responsible for all complaints, compensation and replacement of medicines.

Drug Pricing

1. All drugs should be brought under price control given the fact drug expenditure in India is more than half the health care expense and also because more than 80% of health care expenditure is met by patients themselves. Mechanisms that are transparent and easy to administer should be put in place to control prices and the system of price control should benefit the efficient producer. In no case should the mark up allowed be more than 100%.
2. Trade margin, those to including wholesalers and retailers should not go beyond 30%.
3. National Medicines Pricing Authority should be established as a quasi judicial body which should be given sufficient legal power to punish manufacturer for violation of ceiling prices.
4. For imported medicines, provision of cost data and manufacturers price certificate should be made mandatory.
5. All cancer and HIV/AIDS medicines and orphan medicines should be exempt from all taxes and duties, including import duties.

Public Sector

The production of drugs for the poor and the neglected diseases can only be ensured by making public sector companies major producers in these areas. Public sector medicine companies such as IDPL and HAL should be revived and they should be provided with the support in the form of sectoral reservation, preferential treatment in the cases of Govt. purchases, etc. These companies would need to be provided a leading role in drug manufacture in the case of compulsory licenses issued in situations of national emergency and extreme urgency. New public sector companies should be promoted for producing those essential medicines that are not being produced by private companies at an affordable cost.

Research and Development

1. A major national effort should be made to increase original drug research based on the strength of our national research institutes, laboratories and the Universities and also on the biodiversity and the medicinal plant wealth of our country. The research institutions should be provided with adequate funds for drug research .Regional drug research centres may be established in states where infrastructural facilities are already available. Universities should be encouraged to offer

courses so as to produce adequate and high quality human resource pool for modern drug research related activities. The Public Sector should be promoted to play the leading role in R&D activities.

2. Public funded Research Laboratories should co-ordinate their activities. The research activities of publicly funded research organisations should not duplicate empirical drug discovery projects in the pharma R&D model, but should concentrate on generating the knowledge base for the identification and exploitation of new intervention points for medicines.
3. All medicines developed in the country should be exempt from taxes and duties for 10 years.
4. A comprehensive legislation on the ethical conduct of clinical trials should be enacted in line with the Helsinki Declaration and other international covenants, treaties and declarations so as to provide for strict guidelines for obtaining informed consent, for protection of the health of subjects of such trials.
5. Outsourcing of clinical trials for MNCs should be closely monitored by a specially constituted Standing Ethics Committee set up in each state.
6. All information about protocols and the results of the clinical trials approved by the DGCI should be in the public domain.
7. Phase IV of the clinical trials should be mandatory and should not be replaced by the PMS studies by the pharmaceutical companies.

Quality Control and Drug Information

1. The manufacturer should be fully responsible for the quality of a medicine. A separate Food and Drug Court should be made responsible for redressal of complaints and for trial of those responsible for manufacture and sale of spurious and sub-standard drugs.
2. The Drugs and Cosmetics Act should be suitably amended to provide for exemplary punishment to those found guilty.
3. The drugs control organisation both at state and central levels should be adequately strengthened in terms of infrastructural facilities and human resources.
4. Each state should have at least one well equipped drug testing laboratory under the control of the state drug controller.
5. The state and central drugs controllers should have their own websites. Among other information these websites should publish updated information on banned and withdrawn drugs including their brand names as well the current laws in operation.
6. A consensus should be developed after discussion with manufacturers of all sectors for developing minimum benchmark of good manufacturing practice which then can be embodied in the Schedule 'M' of the Drugs & Cosmetics Act.
7. Consumers should be allowed to get tested medicines of doubtful quality at any Govt. approved test laboratory.
8. New colleges of pharmacy should be opened to eventually ensure that all retail pharmaceutical outlets have the services of a trained pharmacist.
9. The outdated Magic Remedies Act should be replaced by a new Act.

10. To disseminate unbiased information of medicines, Govt. should develop an independent process for information. The National Formulary should be updated and published regularly. Standard treatment protocols and guidelines for common ailments and for every tier of the health system should be prepared and disseminated. Doctors, pharmacists and staff nurses should be trained in treatment protocols and guideline. All hospitals and medical centres should be encouraged to prepare and use their own formularies.

Drug Promotion

1. A National Ethics Committee on Promotion of Medicines (NECPM) in which there is adequate representative of civil society organisations should be formed to monitor all promotional efforts
 2. A code of ethics for marketing of medicines should be adopted by NECPM and made obligatory for all the manufacturers.
 3. All promotional materials for health professionals should be screened and approved by NECPM and all advertisements in the regional press be scrutinized and approved by a state level Ethical Promotion Committee.
 4. Gifts except minor items, inducements, sponsoring of meetings and entertainment of the members of the medical profession and those who are related to drug prescription, purchase etc by drug companies should be banned so that these do not influence prescribing practices.
 5. Drug companies should contribute funds to the drug control authority for the conduct of Continuing Medical Education programme for doctors
 6. A cap on drug promotional expenditure drug companies should be fixed and enforced.
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